

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Before the Board of Patent Appeals and Interferences

In re the Application of

Inventor : **Kevin Wickline et al.**
Application No. : **10/599,312**
Filed : **September 25, 2006**
For : **ULTRASONIC PROBE VOLUME COMPENSATION
SYSTEM**

APPEAL BRIEF

**On Appeal from Group Art Unit 3777
Examiner Vani Gupta**

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I. REAL PARTY IN INTEREST

The real party in interest is Koninklijke Philips Electronics N.V., Eindhoven, The Netherlands by virtue of an assignment recorded on September 25, 2006 at reel 018299, frame 0323.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

The Application was originally filed with Claims 1-18. Following several amendments including the temporary allowance of Claims 2-5 and 7-17 and a request for continued examination, Claims 1-18 have been finally rejected. by an Office Action mailed on January 5, 2012. A Notice of Appeal was timely filed on March 30, 2012. The claims being appealed are Claims 1-18.

IV. STATUS OF AMENDMENTS

No amendments were submitted in response to the final rejection of January 5, 2012.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Ultrasonic transducer probes for medical diagnostic imaging may be categorized as being of two different types: solid-state probes with no moving parts, with the ultrasound beams being steered electronically over a region to be imaged; and mechanical probes in which the ultrasound transducer is mechanically oscillated back and forth to sweep a beam over the region to be imaged. The present invention relates to mechanical probes.

In order to mechanically sweep a transducer back and forth inside a probe, there needs to be a mechanism to oscillate the transducer and a space inside the probe in which the transducer can move back and forth. Because ultrasound at imaging frequencies is rapidly attenuated by air, the space in which the transducer is located must be fluid-filled,

usually with a fluid that closely matches the acoustic impedance of the body such as mineral oil. While the fluid inside the probe is not normally pressurized, problems can develop when the probe is transported by plane and subject to low atmospheric pressure in an airplane cargo compartment, and if the probe is stored in a vehicle in the sun where it experiences high ambient temperatures. In either case the fluid inside the probe will expand. Under such conditions leaks can develop in the probe and under severe conditions the probe can burst. One way to prevent such developments is to provide a small balloon connected to the fluid chamber which is partially filled with fluid under normal conditions. When the fluid in the chamber expands, the balloon can fill further, accommodating the expansion of fluid due to either pressure or temperature changes. The present inventors have discovered that a thin-walled balloon of high performance thermoplastic material provides an ideal set of performance features for an ultrasound probe. This material is very compliant when partially filled, and provides no resistance to being filled with additional fluid. It is also impermeable to most of the fluids used in ultrasound probes. It exhibits high stability to temperature changes, remaining highly compliant even in low temperatures. It also resists stretching when filled and will return to its original size after being filled.

Comparing independent Claims 1 and 10 to the drawings and specification, it is seen that the claims are supported by reference numerals (#) of the drawings and the specification text (pg., ln.) as follows:

1. An ultrasonic probe comprising:
 - a transducer {#46; pg. 4, ln. 30-32} located at a distal end of the probe, the transducer being moved within the chamber to scan an image region outside the probe;
 - a fluid chamber {#42; pg. 5, ln. 24-26} enclosing the transducer within the probe;
 - an acoustic fluid {pg. 5, ln. 19-30} which is highly transmissive of ultrasound located in the fluid chamber; and
 - a thin-walled volume compensation balloon {#44; pg. 6, ln. 1-4} formed of a high performance thermoplastic material, and located completely within the probe in fluid communication with the fluid chamber, the volume compensation

balloon containing a small fraction of the fluid of the fluid chamber at room temperature.

10. An ultrasonic probe for three dimensional imaging comprising:

a probe body {#32; pg. 4, ln. 23-32, pg. 5, ln. 19-23} enclosing a fluid chamber;

an array transducer {#46; pg. 4, ln. 30-32} movably mounted within the fluid chamber;

a drive mechanism {#48, #50; pg. 4, ln. 30 - pg. 5, ln. 9} coupled to the array transducer to move the array transducer during scanning;

an acoustic fluid {pg. 5, ln. 19-30} located within the fluid chamber; and

a volume compensation balloon {#44; pg. 6, ln. 1-31} located completely within the probe and in fluidic communication with the fluid chamber, the balloon being formed of a substantially non elastic material and being partially expanded at room temperature.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether Claims 1 and 9 were properly rejected under 35 U.S.C. §102(c) as being anticipated by US Pat. 7,081,113 (Sutton)

B. Whether Claims 2-5 and 7-9 were properly rejected under 35 U.S.C. §102(b) as being anticipated by US Pat. appl. 2003/00883653 (Maguire et al.)

C. Whether Claims 10-16 and 18 were properly rejected under 35 U.S.C. §102(b) as being anticipated by US Pat. 5,882,302 (Driscoll, Jr. et al.)

D. Whether Claim 6 was properly rejected under 35 U.S.C. §103(a) as being unpatentable over Maguire et al.

E. Whether Claim 17 was properly rejected under 35 U.S.C. §103(a) as being unpatentable over Driscoll, Jr. et al.

VII. ARGUMENT

A. Whether Claims 1 and 9 were properly rejected under 35 U.S.C. §102(e) as being anticipated by US Pat. 7,081,113 (Sutton)

Claims 1 and 9 were rejected under 35 U.S.C. §102(e) as being anticipated by US Pat. 7,081,113 (Sutton). Amended Claim 1 describes an ultrasonic probe comprising a transducer located at a distal end of the probe, the transducer being moved within the chamber to scan an image region outside the probe; a fluid chamber enclosing the transducer within the probe; an acoustic fluid which is highly transmissive of ultrasound located in the fluid chamber; and a thin-walled volume compensation balloon formed of a high performance thermoplastic material, and located completely within the probe in fluid communication with the fluid chamber, the volume compensation balloon containing a small fraction of the fluid of the fluid chamber at room temperature. Since the volume compensation balloon is formed of a high performance thermoplastic material, it will not stretch as an elastomeric material will. The balloon can therefore be contained in a very small space inside the probe, which is already crowded with the drive mechanism and signal leads to the transducer. Being a thin-walled balloon, little space is consumed by the balloon material itself. At room temperature the volume compensation balloon is limp with only a small fraction of the fluid of the fluid chamber for which it provides volume compensation. If the temperature of the probe increases or the surrounding pressure decreases, the balloon will begin to fill with fluid and compensate for expansion of the fluid in the transducer chamber.

Sutton does not describe an ultrasound probe at all. It describes a therapeutic probe designed to be inserted into spaces in spinal tissue. A helical balloon 41 on the outside of the probe enables the probe to be screwed into its desired location in the body. See col. 9, lines 3-6. A dogbone shaped balloon 313 projecting from the side of the probe can maintain the position of the probe in its desired location. See col. 6, lines 44-55. The Sutton probe has no transducer and no volume compensation balloon located completely inside the probe, nor is one suggested. The Sutton device has no volume compensation balloon at all. For these reasons it is respectfully submitted that Sutton cannot anticipate amended Claim 1.

Claim 9 describes an ultrasonic probe comprising a transducer located at a distal end of the probe, the transducer being moved within the chamber to scan an image region outside the probe; a fluid chamber enclosing the transducer within the probe; an acoustic

fluid which is highly transmissive of ultrasound located in the fluid chamber; and a thin-walled volume compensation balloon located completely within the probe and formed of a high performance thermoplastic material in fluid communication with the fluid chamber, the volume compensation balloon containing a small fraction of the fluid of the fluid chamber at room temperature, wherein the thin-walled balloon exhibits a high compliance of less than 2 psi per ml; a low permeation rate to acoustic fluid of less than 1.0; a high burst strength in excess of 10 atmospheres; and a thermal stability which does not significantly decrease compliance at low temperatures of operation. As previously mentioned, the Sutton probe has no transducer and no volume compensation balloon located completely inside the probe, nor is one suggested. The Sutton device has no volume compensation balloon at all. For these reasons it is respectfully submitted that Sutton cannot anticipate amended Claim 1.

B. Whether Claims 2-5 and 7-9 were properly rejected under 35 U.S.C. §102(b) as being anticipated by US Pat. appl. 2003/00883653 (Maguire et al.)

Claims 2-5 and 7-9 were rejected under 35 U.S.C. §102(b) as being anticipated by US Pat. pub. no. 2003/00883653 (Maguire et al.) Maguire et al. describe an inflatable r.f. ablation catheter with a balloon 210 that expands against the walls of a pulmonary vein, for instance, to hold the catheter in place at a region to be ablated. The balloon is filled with an electrically conductive fluid. An electrode 220 inside the balloon is then energized to ablate a circumferential region of the surrounding vessel wall. See paragraph [0175] of Maguire et al.

Amended Claim 2 describes an ultrasonic probe comprising a transducer located at a distal end of the probe, the transducer being moved within the chamber to scan an image region outside the probe; a fluid chamber enclosing the transducer within the probe; an acoustic fluid which is highly transmissive of ultrasound located in the fluid chamber; and a thin-walled volume compensation balloon located completely within the probe and formed of a high performance thermoplastic material in fluid communication with the fluid chamber, the volume compensation balloon containing a small fraction of the fluid of the fluid chamber at room temperature, wherein the thin-walled balloon is formed of a non elastomeric thermoplastic material. Maguire et al. does not show or suggest an ultrasound probe, the Maguire et al. catheter has no transducer, it performs no scanning of an image region, and it has no volume compensation balloon located inside the catheter. For these

reasons it is respectfully submitted that Maguire et al. cannot anticipate Claim 2 or its dependent Claims 3-5.

Amended Claim 7 describes an ultrasonic probe comprising a transducer located at a distal end of the probe, the transducer being moved within the chamber to scan an image region outside the probe; a fluid chamber enclosing the transducer within the probe; an acoustic fluid which is highly transmissive of ultrasound located in the fluid chamber; and a thin-walled volume compensation balloon located completely within the probe and formed of a high performance thermoplastic material in fluid communication with the fluid chamber, the volume compensation balloon containing a small fraction of the fluid of the fluid chamber at room temperature, wherein the non elastomeric thermoplastic material comprises a PET polymer. Maguire et al. does not show or suggest an ultrasound probe, the Maguire et al. catheter has no transducer, it performs no scanning of an image region, and it has no volume compensation balloon located inside the catheter. For these reasons it is respectfully submitted that Maguire et al. cannot anticipate Claim 7 or its dependent Claim 8.

Amended Claim 9 describes an ultrasonic probe comprising a transducer located at a distal end of the probe, the transducer being moved within the chamber to scan an image region outside the probe; a fluid chamber enclosing the transducer within the probe; an acoustic fluid which is highly transmissive of ultrasound located in the fluid chamber; and a thin-walled volume compensation balloon located completely within the probe and formed of a high performance thermoplastic material in fluid communication with the fluid chamber, the volume compensation balloon containing a small fraction of the fluid of the fluid chamber at room temperature, wherein the thin-walled balloon exhibits a high compliance of less than 2 psi per ml; a low permeation rate to acoustic fluid of less than 1.0; a high burst strength in excess of 10 atmospheres; and a thermal stability which does not significantly decrease compliance at low temperatures of operation. Maguire et al. does not show or suggest an ultrasound probe, the Maguire et al. catheter has no transducer, it performs no scanning of an image region, and it has no volume compensation balloon located inside the catheter. For these reasons it is respectfully submitted that Maguire et al. cannot anticipate Claim 9.

C. Whether Claims 10-16 and 18 were properly rejected under 35 U.S.C. §102(b) as being anticipated by US Pat. 5,882,302 (Driscoll, Jr. et al.)

Claims 10-16 and 18 were rejected under 35 U.S.C. §102(b) as being anticipated by US Pat. 5,882,302 (Driscoll, Jr. et al.) Driscoll, Jr. et al. describes a probe with a rotating transducer member 28 having therapeutic surfaces and an imaging transducer 45. The transducer member 28 is located at the transducer region 30 of the probe which is connected to a reservoir 36. An acoustic membrane 38 made of an inelastic, non-distensible, thin membrane covers the transducer region 30. When the transducer region is held in contact with the body of the patient, the pressure P of the fluid inside is controllably varied to displace the adjacent tissue. This displacement enables elasticity imaging of the underlying tissue. Amended Claim 10 describes an ultrasonic probe for three dimensional imaging comprising a probe body enclosing a fluid chamber; an array transducer movably mounted within the fluid chamber; a drive mechanism coupled to the array transducer to move the array transducer during scanning; an acoustic fluid located within the fluid chamber; and a volume compensation balloon located completely within the probe and in fluidic communication with the fluid chamber, the balloon being formed of a substantially non elastic material and being partially expanded at room temperature. Driscoll, Jr. et al. does not show or suggest a volume compensation balloon for their fluid-filled probe. To the contrary, they have a rigid reservoir 36 which serves as an additional source of fluid for their transducer region 30. The acoustic membrane 30 serves to transmit displacement pulses to the adjacent tissue when the pressure in the transducer region is varied for elasticity imaging. Furthermore, the acoustic membrane is on the outside of the transducer region, not completely inside the probe as called for by Claim 10. Driscoll, Jr. et al. gives no thought to volume compensation at all. For these reasons it is respectfully submitted that Driscoll, Jr. et al. cannot anticipate Claim 10 or its dependent Claims 11-18.

D. Whether Claim 6 was properly rejected under 35 U.S.C. §103(a) as being unpatentable over Maguire et al.

Claim 6 was rejected under 35 U.S.C. §103(a) as being unpatentable over Maguire et al. Claim 6 recites that the acoustic fluid comprises silicone oil. Silicone oil provides lubrication of the moving transducer assembly inside the probe and is non-corrosive, in addition to being highly transmissive of ultrasound. Maguire et al. give no consideration to these factors. Maguire et al. does not involve ultrasound or ultrasound transducers at all.

Maguire et al. describes an r.f. ablation catheter. In addition, Claim 6 depends from Claim 1, and Maguire et al. does not show or suggest an ultrasound probe, an ultrasound transducer, scanning of an image region with a transducer, and Maguire et al. have no volume compensation balloon. For all of these reasons it is respectfully submitted that Claim 6 is patentable over Maguire et al.

E. Whether Claim 17 was properly rejected under 35 U.S.C. §103(a) as being unpatentable over Driscoll, Jr. et al.

Claim 17 was rejected under 35 U.S.C. §103(a) as being unpatentable over Driscoll, Jr. et al.. Claim 17 depends from Claim 10 and, as mentioned above, Driscoll, Jr. et al. does not show or suggest a volume compensation balloon for their fluid-filled probe. To the contrary, they have a rigid reservoir 36 which serves as an additional source of fluid for their transducer region 30. The transducer region 30 is filled with fluid at all times and is not partially expanded at room temperature as called for by Claim 10. Furthermore, the acoustic membrane of Driscoll, Jr. et al. is on the outside of the transducer region, not completely inside the probe as called for by Claim 10. Driscoll, Jr. et al. gives no thought to volume compensation at all. For these reasons it is respectfully submitted that Claim 17 is patentable over Driscoll, Jr. et al..

VIII. CONCLUSION

Based on the law and the facts presented, Appellant respectfully submits that Claims 1-5, 7-16 and 18 are not anticipated by Sutton, Maguire et al., or Driscoll, Jr. et al. and that Claims 6 and 17 are patentable over Maguire et al. and Driscoll, Jr. et al. Accordingly, Appellant respectfully requests that this Honorable Board reverse all grounds of rejection of these claims as stated in the January 5, 2012 Office Action being appealed.

Respectfully submitted,

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APPENDIX A: CLAIMS APPENDIX

The following Claims 1-18 are the claims involved in the appeal.

1. (previously presented) An ultrasonic probe comprising:
 - a transducer located at a distal end of the probe, the transducer being moved within the chamber to scan an image region outside the probe;
 - a fluid chamber enclosing the transducer within the probe;
 - an acoustic fluid which is highly transmissive of ultrasound located in the fluid chamber; and
 - a thin-walled volume compensation balloon formed of a high performance thermoplastic material, and located completely within the probe in fluid communication with the fluid chamber, the volume compensation balloon containing a small fraction of the fluid of the fluid chamber at room temperature.

2. (previously presented) An ultrasonic probe comprising:
 - a transducer located at a distal end of the probe, the transducer being moved within the chamber to scan an image region outside the probe;
 - a fluid chamber enclosing the transducer within the probe;
 - an acoustic fluid which is highly transmissive of ultrasound located in the fluid chamber; and
 - a thin-walled volume compensation balloon located completely within the probe and formed of a high performance thermoplastic material in fluid communication with the fluid chamber, the volume compensation balloon containing a small fraction of the fluid of the fluid chamber at room temperature,

wherein the thin-walled balloon is formed of a non elastomeric thermoplastic material.

3. (original) The ultrasonic probe of Claim 2, wherein the thin-walled balloon exhibits a low permeability to the acoustic fluid.

4. (original) The ultrasonic probe of Claim 3, wherein the thin-walled balloon exhibits a high compliance over the designed temperature range of transport and use.

5. (original) The ultrasonic probe of Claim 4, wherein the thin-walled balloon exhibit a high thermal stability and is operated at or below the glass transition temperature for the thermoplastic material.

6. (original) The ultrasonic probe of Claim 1, wherein the acoustic fluid comprises a silicone oil.

7. (previously presented) An ultrasonic probe comprising:

a transducer located at a distal end of the probe, the transducer being moved within the chamber to scan an image region outside the probe;

a fluid chamber enclosing the transducer within the probe;

an acoustic fluid which is highly transmissive of ultrasound located in the fluid chamber; and

a thin-walled volume compensation balloon located completely within the probe and formed of a high performance thermoplastic material in fluid communication with the fluid chamber, the volume compensation balloon containing a small fraction of the fluid of the fluid chamber at room temperature,

wherein the non elastomeric thermoplastic material comprises a PET polymer.

8. (original) The ultrasonic probe of Claim 7, wherein the thin-walled balloon exhibits a high burst strength.

9. (previously presented) An ultrasonic probe comprising:

a transducer located at a distal end of the probe, the transducer being moved within the chamber to scan an image region outside the probe;

a fluid chamber enclosing the transducer within the probe;

an acoustic fluid which is highly transmissive of ultrasound located in the fluid chamber; and

a thin-walled volume compensation balloon located completely within the probe and formed of a high performance thermoplastic material in fluid communication with the fluid chamber, the volume compensation balloon containing a small fraction of the fluid of the fluid chamber at room temperature,

wherein the thin-walled balloon exhibits a high compliance of less than 2 psi per ml; a low permeation rate to acoustic fluid of less than 1.0; a high burst strength in excess of 10 atmospheres; and a thermal stability which does not significantly decrease compliance at low temperatures of operation.

10. (previously presented) An ultrasonic probe for three dimensional imaging comprising:

a probe body enclosing a fluid chamber;

an array transducer movably mounted within the fluid chamber;

a drive mechanism coupled to the array transducer to move the array transducer during scanning;

an acoustic fluid located within the fluid chamber; and a volume compensation balloon located completely within the probe and in fluidic communication with the fluid chamber, the balloon being formed of a substantially non elastic material and being partially expanded at room temperature.

11. (original) The ultrasonic probe of Claim 10, wherein the balloon is approximately half filled with acoustic fluid at room temperature.

12. (original) The ultrasonic probe of Claim 11, wherein the balloon contains less than 20% of the fluid of the fluid chamber at room temperature.

13. (original) The ultrasonic probe of Claim 10, wherein the balloon is formed of a high performance thermoplastic.

14. (original) The ultrasonic probe of Claim 13, wherein the balloon is formed of a PET polymer.

15. (original) The ultrasonic probe of Claim 10, wherein the compliance of the wall of the balloon is substantially constant over a design temperature range of transport and use.

16. (original) The ultrasonic probe of Claim 15, wherein the design temperature range of use extends below 0°C.

17. (original) The ultrasonic probe of Claim 10, wherein the wall thickness of the balloon is less than 1.0 mil, and wherein the wall of the balloon exhibits a low permeability to the acoustic fluid.

18. (original) The ultrasonic probe of Claim 10,
wherein the probe body comprises a shaft designed for
intracavity use of the probe.

APPENDIX B: EVIDENCE APPENDIX

No additional evidence is provided in this Appeal.

APPENDIX C: RELATED PROCEEDINGS APPENDIX

None. There are no related proceedings.